K060409 page 1/2

510(k) Summary

MAY 17 2006

510(k)'s Owner Name: Vanson HaloSource, Inc.
Address: 14716 NE 87th Street, Redmond, WA 98052
Phone Number: 425.881.6464
Fax Number: 425.882.2476
Contact Person: Eric Robinson, VP Operations
Date of Preparation: February 14, 2006

Trade Name: HemoHalt™ Hemostasis Pad Wound Dressing
Common Name: Wound Dressing
Classification: Unclassified
Product code: FRO
Classification Name: Dressing

Device Description: HemoHalt™ Hemostasis Pad is a soft, non-woven pad approximately 5 x 5 x 0.5cm in size, made of chitosan, a polysaccharide heteropolymer of poly-D-glucosamine and poly-N-acetyl-D-glucosamine. The HemoHalt™ Hemostasis Pad will be packaged in a paper surfaced, high barrier foil pouch for single use and terminally sterilized by E-beam radiation.

Intended Use: The HemoHalt™ Hemostasis Pad is intended for the local management and rapid control of bleeding (hemostasis): for skin surface puncture sites for vascular procedures, percutaneous catheters and/or tubes; following hemodialysis treatments; for patients on anticoagulation therapy; and for lacerations, abrasions, and nose bleeds. For use only on external bleeding wounds.

Summary of Technological Characteristics:

The comparison between the HemoHalt™ Hemostasis Pad Wound Dressing and the predicate device can be summarized as follows. None of the differences raise any concerns regarding safety or effectiveness.

	HemoHalt™ Hemostasis Pad Wound Dressing	**Predicate Device**	**Comparison**
Intended Use	Intended for the local management and rapid control of bleeding (hemostasis): for skin surface puncture sites for vascular procedures, percutaneous catheters and/or tubes; following hemodialysis treatments; for patients on anticoagulation therapy; and for lacerations, abrasions, and nose bleeds. For use only on external bleeding wounds.	Intended for use under the direction of a health care professional for the following indications: The predicate is indicated for the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy. The predicate is indicated for use in the local management of bleeding wounds such as vascular access sites, percutaneous catheters or tubes, and surgical debridement.	Same
Composition	Chitosan, a polysaccharide heteropolymer of poly-D-glucosamine and poly-N-acetyl-D-glucosamine	polysaccharide homopolymer, poly-N-acetyl-D-glucosamine	Differs in source with some differences in structure
Physical Dimensions	5 x 5 x 0.5cm	1.2" x 1.2" (3 x 3 cm)	Differs in size
Form	Non-woven	Non-woven	Same
Sterile	Yes, terminal sterilization	Yes, terminal sterilization	Same
Packaging Material	Foil pouch	Foil pouch	Same
Packaging Type	Single use	Single use	Same
Duration of Use	Short term	Short term	Same
Type of Use	Topical	Topical	Same

Performance Comparison: *In vivo* and *in vitro* tests were performed comparing the HemoHalt™ Hemostasis Pad with the predicate. The results indicate that the HemoHalt™ Hemostasis Pad performs as well as or better than the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

Vanson-HaloSource
% Mr. Eric Robinson
Vice President of Operations
14716 NE 87th Street
Redmond, Washington, 98052

Re: K060409
Trade/Device Name: HemoHalt™ Hemostasis Pad Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 17, 2006
Received: April 19, 2006

Dear Mr. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060409

Device Name: HemoHalt™ Hemostasis Pad Wound Dressing

Indications for Use:

The HemoHalt Hemostasis Pad is intended for the local management and rapid control of bleeding (hemostasis): for skin surface puncture sites for vascular procedures, percutaneous catheters and/or tubes; following hemodialysis treatments; for patients on anticoagulation therapy; and for lacerations, abrasions, and nose bleeds. For use only on external bleeding wounds.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K060409